

TCT-593**Gender Difference in Chest Pain After Implantation of Newer Generation Coronary Drug-Eluting Stents: A Patient-Level Pooled Analysis From TWENTE and DUTCH PEERS**

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BACKGROUND Gender-based data on chest pain after PCI with newer generation DES are scarce. The aim of this study is to assess gender differences in chest pain following percutaneous coronary intervention (PCI) with newer generation drug-eluting stents (DES).

METHODS We performed a patient-level pooled analysis of the TWENTE and DUTCH PEERS randomized trials that enrolled a broad patient population, treated with newer generation permanent polymer-coated DES. The primary clinical endpoint is target vessel failure (TVF), a composite of cardiac death, target vessel-related myocardial infarction (MI), or target vessel revascularization. At 1 and 2-years, clinical follow-up was available in 99.9% and patient-reported chest pain data in 94.1% and 93.6%.

RESULTS Among all 3,202 patients, the 871 (27.2%) women were older (67.5±10.2 years vs. 62.8±10.6 years, $p<0.001$) and had more cardiovascular risk factors than men, such as diabetes (24.2% vs. 17.8%, $p<0.001$), hypertension (63.6% vs. 51.6%, $p<0.001$), and a positive family history for coronary disease (54.5% vs. 50.1%, $p=0.03$). At 1 and 2-year follow-up, women had more clinically relevant chest pain than men (16.3% vs. 10.5%, $p<0.001$, and 17.2% vs. 11.1%, $p<0.001$, respectively). Multivariate analysis demonstrated that female gender independently predicted clinically relevant chest pain at 1 and 2-year follow-up (adjusted OR:1.7, 95%-CI:1.4-2.2, $p<0.001$; adjusted OR:1.6, 95%-CI:1.3-2.1, $p<0.001$, respectively). Nevertheless, the 2-year rates of TVF (9.4% vs. 9.5%, $p=0.93$) were almost identical for both genders.

CONCLUSIONS While after PCI with newer generation DES the incidence of adverse cardiovascular events was low and similar for both genders, women showed a significantly higher prevalence of clinically relevant chest pain that appears to be largely related to mechanisms other than epicardial coronary obstruction.

CATEGORIES OTHER: Womens Health Issues

KEYWORDS Chest pain, Gender, Percutaneous coronary intervention

TCT-594**Initial Report Of The ASCENT Registry: Observational Experience With The New Alpha Coronary Stent**

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BACKGROUND The ALPHA coronary stent delivery system includes a cobalt-chromium, flexible, thin-strut platform, a bio-stable and biocompatible fluoro-polymer based drug carrier, sirolimus and a hydrophilic, rapid-exchange delivery catheter. It is designed to create a competitive alternative to other drug-eluting coronary stents systems. Herein, we report the initial 2-year outcomes of 781 patients (pts) treated with the ALPHA stent.

METHODS Consenting pts. were treated with one or more ALPHA stents and followed by trained research coordinators. Angiographic and follow-up angiography was evaluated by a central angiographic core laboratory.

RESULTS Pts. averaged 58 years of age and 66% were male. Hypertension was present in 57%. Most pts. presented with unstable angina (78%). Sites of stent implantation included the LAD (55%), LCX (20%) and RCA (25%). Based on angiographic core lab measurements, average lesion length was 21 mm and average reference diameter was 2.8mm. Most pts. (69%) had a single lesion treated and 1.6 stents were deployed per pt. Transradial access was used in 83%. Two-year follow-up was available in 768 (98%) pts. The incidence of all-cause death was 0.9% with cardiac death being 0.4%. The rate of target lesion revascularization was 0.7%. Myocardial infarction was observed in 1.3%. Importantly total MACE was 2.2% and no pt.

experienced thrombosis of the Alpha stent. Angiographic follow-up was completed in 87% of 205 pts. Lesion length and reference diameter were 21±13 mm and 2.8±0.7mm respectively. In-stent late loss was 0.07 mm and in-segment late loss was 0.04± mm. Binary restenosis rate was 1.0%.

CONCLUSIONS The ALPHA stent was designed on the basis of the most contemporary knowledge of stent technology. This observational study demonstrates the ALPHA stent can achieve high rates of sustained patency with low rates of stent-related adverse events.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Stent, Stenting, coronary

TCT-595**Randomized Comparison Of The New ALPHA And The EXCEL Stents: Outcomes And Significance Of Biodegradable Polymers In Preventing Stent Thrombosis**

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BACKGROUND Stent thrombosis (ST) is an undesirable consequence of intracoronary stents, commonly presenting as myocardial infarction and at times death. Efforts to reduce the occurrence of ST have included the use of biodegradable polymers. Whether this modification of stent design reduces ST is unclear

METHODS The ALPHA coronary stent includes a flexible, cobalt-chromium platform, a bio-stable and bio-compatible fluoro-polymer based drug carrier and sirolimus. We conducted a randomized, single blinded trial to compare the angiographic (9-months) and clinical (12-months) outcomes of ALPHA (n=205) to EXCEL (n=202), also a sirolimus eluting stent but with a bio-degradable polymer.

RESULTS There were no significant ($p>0.05$) differences in baseline clinical or angiographic features, number of stents deployed or initial success rates. At 9-months, angiographic late loss (angiographic core laboratory, LL) was 0.07 mm and 0.10 mm ($P=NS$) in ALPHA and EXCEL stents respectively. Maximal LL across stent segments was lower in ALPHA compared to EXCEL patients (0.20mm vs. 0.25mm, $p=0.02$). At 12-months, clinical events were low in both stent groups (table). No patient receiving the ALPHA stent experienced ST while ST was observed in 0.5% of those treated with EXCEL.

CONCLUSIONS Excellent angiographic and clinical results, including avoiding stent thrombosis, may be obtained with the ALPHA sirolimus eluting stent and a stable polymer.

Event at 12-months	ALPHA	EXCEL	P value
All Cause Death	0.5%	1.0%	0.22
Myocardial Infarction	1.0%	1.5%	0.69
Any TLR	1.5%	3.0%	0.09
ARC Thrombosis	0%	0.5%	0.50

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Sirolimus, Stent development, Stent thrombosis, late

TCT-596**Dose Dependent Vascular Response Following Delivery Of Sirolimus Via Fast Releasing, Biodegradable Polymer Stent Matrix: An Experimental Study In The Porcine Coronary Model Of Restenosis**

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BACKGROUND Fast releasing, rapamycin eluting stents although safe, showed inferior results with regard to inhibition of restenosis. Therefore, we report vascular effects of the novel, biodegradable polymer stent matrix with elevated sirolimus dose and fast release kinetics (ed-frSES, Alex, Balton) in the porcine coronary in stent restenosis model.

METHODS A total of 19 stents were implanted with 120% overstretch in coronary arteries of 7 domestic pigs: 7 ed-frSES with 1.3 µg/mm² of